Drug Reimbursement in Australia: Through the looking glass

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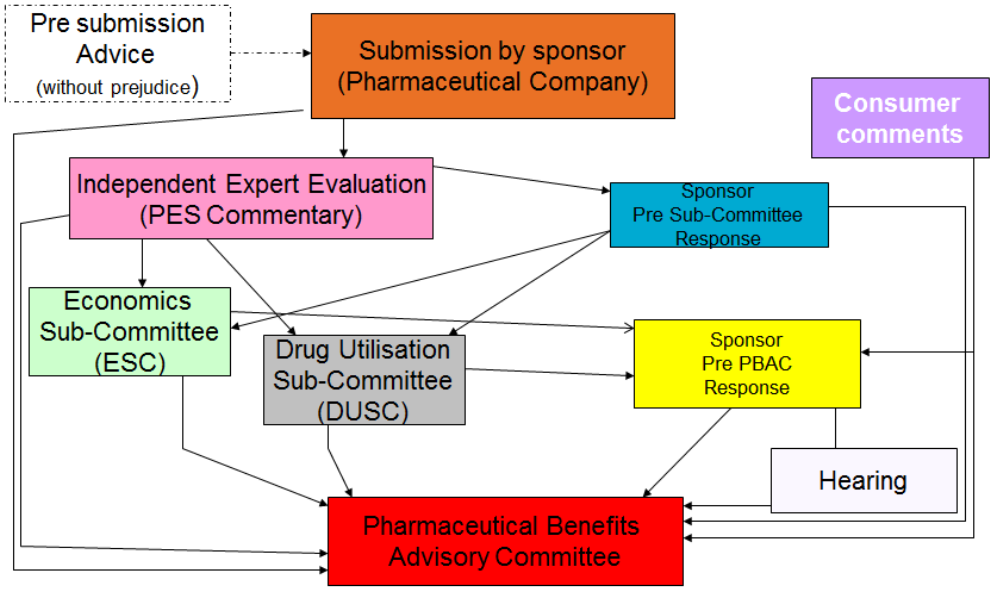
The PBAC Process

The submission process to PBAC takes **17 weeks** from the time of submission to the consideration of the submission by PBAC. Following this, the post PBAC process can include price negotiations, risk share negotiations, cabinet approval or re-submission.



Source: Richard De Abreu Lourenco presentation, 19 February 2015.

Throughout this process consumers have the opportunity to strengthen a submission in multiple ways. The following considerations can be made when involving consumers in the PBAC submission process:

- Consumer involvement can **be partnered** with the collection of evidence/use of data by the sponsor as opposed to being submitted in isolation
- Consumer involvement allows the submission to demonstrate how the availability or unavailability of a drug can impact an individual's **quality of life**

What is it like to have that condition?

How does it impact on everyday life?

What are the effects of the new drug?

Are there issues with accessing the current treatment?

PBAC Decision factors

The table below outlines the factors considered by PBAC in the approval of a submission and the questions associated with these factors.

Decisive factor	Questions to consider
Cost-effectiveness	How is this drug better than the current treatment options? Are the clinical gains of the new drug sufficient? Can the price be modified? Can the duration of the availability of the drug be modified?
Strength of clinical data	Is the evidence relevant? Does it reflect the patient experience? **Hint:** Include evidence from RCT trials (where possible) as these are preferred by PBAC.
Affordability (patients and society)	Could patients afford the drug if it wasn't listed? Could society afford the associated costs if the drug was listed?
Confidence in information	What are the sources of information? Are clinical data available? Are the data on costs and economic evidence sound?
Equity of access and covered	How many people might be treated by this drug? Who will be treated by this drug? How will the drug be made available?
Medical need/availability of alternatives	Are there other treatments currently available? How are the currently available alternatives administered?
Ability to target	Can the availability of the drug be targeted to those that are most likely to benefit? What are the consequences if the drug is available to people outside this target group? **Hint:** This is known as "leakage" and refers to when a drug is used outside the targeted patient group it is intended for.

Did you know?

Q. Who is the sponsor?

A. A sponsor of a submission is not necessarily the manufacturer of the drug. Anyone can be the sponsor of a submission. However, if the submission is about the manufacturing of a new drug, the sponsor needs to be able to manufacture and/or market the drug.

Q. What is the difference between a minor and major submission?

A. An evaluation (and a couple of hundred pages!)

Q. Is international evidence useful for a PBAC submission?

A. Yes. International evidence and clinical trials that are extrapolated and applied to the Australian context can provide strong evidence in a PBAC submission. PBAC is pragmatic in is approach to international evidence but will not approve a drug for the Australian context based on its approval elsewhere.

Q. Is it worthwhile submitting consumer information in the absence of a submission from the sponsor?

A. While consumer information can be submitted without an accompanying submission from the sponsor, it is very unlikely to result in a change. It is recommended that consumer information be submitted at the same time as evidence/data of a sponsor's submission.

Q. Where is information about current submissions?

A. PBAC publishes its monthly agenda approximately 6 – 8 weeks prior to the meeting. The agenda can be found on the PBAC website: http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/agenda

Q. Where can further questions be answered?

A. The Department of Health has the contact details of the following groups available on their website:

- HTA Access Point (HTAAP)
- Therapeutic Goods Administration (TGA)
- Prostheses List Advisory Committee
- Pharmaceutical Benefits Advisory Committee (PBAC)
- Medical Services Advisory Committee (MSAC)

The contact details can be found here: http://www.health.gov.au/internet/hta/publishing.nsf/Content/contacts-1